Goal 3: Safe Food

The foods Americans eat will be free from unsafe pesticide residues. Particular attention will be given to protecting subpopulations that may be more susceptible to adverse effects of pesticides or have higher dietary exposures to pesticide residues. These include children and people whose diets include large amounts of noncommercial foods.

Background and Context

The United States Environmental Protection Agency (EPA) plays a major role in the lives of the American public by ensuring that agricultural use of pesticides will not result in unsafe food. EPA accomplishes this by registering new pesticide products and reviewing older pesticide products by strict standards that protect human health and the environment from risks associated with pesticide use.

EPA uses the latest scientific information to ensure that there is "a reasonable certainty" that no harm will result to human health from all combined sources of exposure to pesticides (aggregate exposures). Moreover, it submits for review its critical risk assessment science issues, its methodologies for toxicity testing and related science issues, to the Science Advisory Panel (SAP), an independent, expert advisory committee. The SAP plays a critical role in EPA's decision-making process, assuring that decisions impacting health and the environment rely on sound science.

The potential risk of adverse effects to consumers from pesticide residues in foods is a primary concern for the Agency, as is the potential bioconcentration of certain pesticides in plant and animal tissues that may result in even higher levels of exposure. Critical to protecting human health is the review of food use pesticides for potential toxic effects such as birth defects, cancer, disruption of the endocrine system, changes in fertility, harmful effects to the kidneys and liver, and nervous system bioaccumulation. Under Goal 3, the Safe Food goal, EPA ensures that any residues on food do not exceed established limits.

All pesticides are subject to EPA regulation including insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators, plant incorporated protectants and other substances intended to control pests. Pesticides are used in agriculture, greenhouses, on lawns, in swimming pools, industrial buildings, households, and in hospitals and food service establishments. The total United States pesticide usage in 1999 was 5 billion pounds.[1]

EPA's Pesticide Regulations Affect a Cross Section of the US Population

- 18 major pesticide producers and another 100 smaller producers
- 2,200 formulators
- 33,100 commercial pest control firms
- 1.9 million farms
- Several million industry and government users
- About 77 million households

Source: EPA's 1998/1999 Pesticides Sales and Usage Report[1]

Agriculture accounts for about 80 percent of all pesticide applications. Herbicides are the most widely used pesticides and account for the greatest expenditure and volume, approximately $6.4 billion and 534 million pounds in 1999. Biopesticides and reduced risk pesticides are assuming an increasingly important role. For example, safer pesticides, which include biopesticides and reduced risk pesticides, increased in use from 3.6% in 1998 to 7.5% of total pounds reported for 2002.[2]

EPA regulates pesticides under two main statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food and Drug Cosmetic Act (FFDCA). FIFRA requires pesticides to be registered (licensed) by EPA before they may be sold or distributed in the United States, and that they perform their intended functions without causing unreasonable adverse effects to people or the environment when used according to EPA-approved label directions. At the same time, recognizing the role of pesticides in ensuring a diverse, abundant and affordable food supply, EPA works to streamline its licensing procedures and increase transparency in the review process.

[1] Ibid.
[2] Doane Marketing Research, Inc.: http://www.doanemr.com

FFDCA authorizes EPA to set tolerances, or maximum legal limits, for pesticide residues in or on food. Tolerance requirements apply equally to domestically produced and imported food. Any food with residues not covered by a tolerance, or in amounts that exceed an established tolerance, may not be legally marketed in the United States.

Amendments to both FIFRA and FFDCA by the Food Quality Protection Act (FQPA) of 1996 enhance protection of children and other sensitive sub-populations. FQPA establishes a single, health-based safety standard for all pesticide residues. The agency-wide FY 2004 request supporting FQPA includes $150 million for EPA's work under these laws, enabling the public to enjoy one of the safest, most abundant, and most affordable food supplies in the world. FQPA also enhanced EPA's ability to protect human health and the environment in several other ways, including:

- Providing for a more complete assessment of potential risks, with special protections for sensitive groups, such as infants and children;
- Improvement of antimicrobial registration process and establishment of tolerances for food use inert ingredients;
- Expediting the approval of reduced risk pesticides;
- Encouraging farmers' adoption of safer pest management practices;
- Ensuring that pesticides are periodically reassessed for consistency with current safety standards and the latest scientific and technological knowledge; and
- Educating consumers about pesticide risks and benefits.

Means and Strategy

The Agency's strategy for accomplishing the objectives of Safe Food is based on five pillars, four of which are in Goal 3 and one is in Goal 4. Under Goal 3, the EPA is:

- Assuring that new chemicals and new uses are registered in accordance with the FQPA's strict standard, a "reasonable certainty of no harm," so that no harm will result to human health from exposure to pesticides;
- Assuring that pesticide maximum legally allowable tolerances for foods eaten by children are in conformance with FQPA requirements that protect children;
- Re-evaluating older, potentially higher-risk pesticides using the best current scientific data and methods to determine whether additional limits on a pesticides use are needed to provide reasonable certainty of no harm, especially for children and other sensitive populations; and
- Expediting review and registration of alternative pesticides that are less risky than pesticides currently in use and that may be substituted effectively for higher risk pesticides.

New registration actions result in more pesticides on the market that meet the strict FQPA pesticide risk-based standards, which brings the Agency closer to the objective of reducing adverse risks from pesticide use. In 2004, the Agency will continue to promote accelerated registrations for pesticides that provide improved risk reduction or risk prevention compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing adverse impact on health and the ecosystem while preserving food production rates.

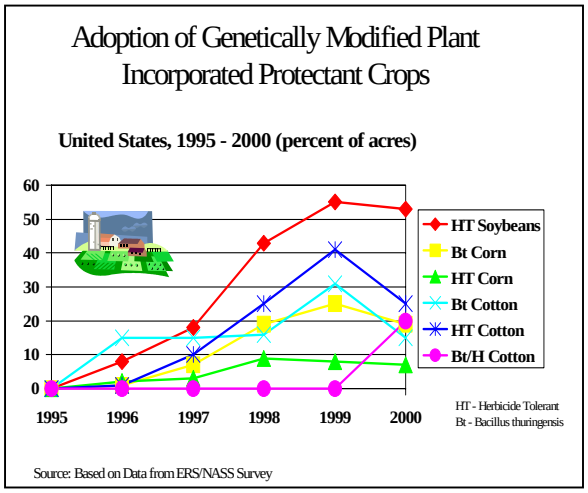
EPA uses its authorities to manage systematically the risks of pesticide exposures by establishing legally permissible food-borne pesticide residue levels, or tolerances. EPA defines the legal use of pesticides, up to and including the elimination of pesticides that present a danger to human health and the environment. This task involves a comprehensive review of new and existing pesticides as stipulated by the FIFRA mandated registration and reregistration programs, as well as a comprehensive reassessment and update of existing tolerances within ten years, as required by FQPA. Requested resources include enhancing the efforts to review antimicrobials as well as inert ingredients, in order to meet the FQPA deadlines. In FY 2004, EPA will also increase support for the homeland security activities related to identifying antimicrobials that are effective against potential bio-agents that could be used against the United States

Tolerance reassessments may mean mandatory use changes because a revision in the allowable residue levels can

involve changes in pesticide application patterns, changes in the foods the pesticides may be applied to, and other risk management methods. As measured by the number of tolerances that have been reassessed, the Agency's progress in the tolerance reassessment program directly serves the objective of reducing the use on food of pesticides that do not meet the new standards. EPA uses the latest scientific advances in health-risk assessment practices in its reviews. This includes the incorporation of new scientific data relating to the effects of endocrine disruption and the special needs of susceptible populations such as children and Native Americans.

Biotechnology has presented the Agency with a range of new issues and scientific challenges as well. Outreach activities on the subject of biotechnology such as public meetings and scientific peer reviews of our policies and assessments are likely to be expanded to keep pace with changing science and the public's demand for information in this area. EPA is working closely with other Federal agencies involved in biotechnology and is also actively involved in developing international standards for the regulation of biotechnology products.

Biotechnology is becoming increasingly more important in our economy with bio-engineered plants accounting for a larger share of acres planted than ever before in the United States. For example, in 1996, Herbicide Resistant (HT) Soybeans accounted for only eight percent of the total United States acres planted in soybeans. In 2000, HT



Soybeans accounted for 53 percent of the acres planted for other crops. Trends also indicate increases, though not as dramatically as for soy. (See chart.)[3]

Adoption of biotechnology has great potential to reduce reliance on some older, more risky chemical pesticides, and to lower worker risks. For example, the use of Bt cotton has affected the use of other insecticides that present higher risk to wildlife. According to the reported number of insecticide treatments per planted acre of cotton, use of insecticides labeled either toxic or extremely toxic to wildlife has undergone significant reduction since 1995, with the extremely toxic pesticides decreasing from 1.6 to 0.5 acre treatments, a 68% reduction.

In addition to setting the requirements for continued legal use of agricultural pesticides, EPA works in partnership with USDA, FDA and the states toward the broader effort to prevent the misuse of pesticides. In the ever-changing environment of pesticide use, accessibility to information is a primary component of an effective strategy to inform the public on the appropriate, safe use of pesticides to minimize risk. More information about EPA's food safety efforts is available on the Agency's website at http://www.epa.gov/pesticides.

Research

Current approaches to human health risk assessment focus on single pesticides and do not adequately account for cumulative risks arising from complex exposure patterns and human variability due to age, gender, pre-existing disease, health and nutritional status, and genetic predisposition. The Food Quality Protection Act (FQPA) identifies clear science needs, including the evaluation of all potential routes and pathways of exposures to pesticides, and resulting health effects, particularly for sensitive sub-populations and considering effects from cumulative exposures.

To support the FQPA, tools are needed for assessing aggregate and cumulative risks across the exposure-to-dose-to-effects continuum that result from multimedia, multipathway exposures to pesticides with like mechanisms of action. Research is also needed to further understand the magnitude and extent of aggregate and cumulative exposures of pesticides used on food, in drinking water, and through non-occupational exposures in and around residential environments and other indoor/outdoor environments. Special emphasis will be placed on characterizing exposures and the corresponding critical factors influencing these exposures in those environments where young children spend the majority of their time.

Several mechanisms are in place to ensure a high-quality research program at EPA. The Research Strategies

[3] ERS/NASS Survey: http://www.usda.gov/nass

Advisory Committee (RSAC) of EPA's Science Advisory Board (SAB), an independent chartered Federal Advisory Committee Act (FACA) committee, meets annually to conduct an in-depth review and analysis of EPA's Science and Technology account. The RSAC provides its findings to the House Science Committee and sends a written report on the finding to EPA's Administrator after every annual review. Also, under the Science to Achieve Results (STAR) program all research projects are selected for funding through a rigorous competitive external peer review process designed to ensure that only the highest quality efforts receive funding support. In addition, EPA's scientific and technical work products must undergo either internal or external peer review, with major or significant products requiring external peer review. The Agency's Peer Review Handbook (2nd Edition) codifies procedures and guidance for conducting peer review.

External Factors

The ability of the Agency to achieve its strategic objectives depends on several factors over which the Agency has only partial control or little influence. EPA relies heavily on partnerships with states, tribes, local governments and regulated parties to protect the nation's food supply, the environment, and human health, from pesticides.

EPA assures the safe use of pesticides in coordination with the USDA and FDA, who have responsibility to monitor and control residues on food and other environmental exposures. EPA also works with these agencies to coordinate with other countries and international organizations with which the United States shares pesticide-related environmental goals. The Agency employs a number of mechanisms and programs to assure that our partners will have the capacity to conduct the activities needed to achieve the objectives. Much of the success of EPA's pesticide programs also depends on the voluntary cooperation of the private sector and the public.

Other factors that may delay or prevent the Agency's achievement of the objectives include lawsuits that delay or stop the planned activities of EPA and/or state partners, new or amended legislation and new commitments within the Administration. Economic growth and changes in producer and consumer behavior could also have an influence on the Agency's ability to achieve the objectives within the time frame specified.

Large-scale accidental releases, such as pesticide spills, or rare catastrophic natural events (such as hurricanes or large-scale flooding) could impact EPA's ability to achieve objectives in the short term. In the longer term, the time frame for achieving many of the objectives could be affected by new technology or unanticipated complexity or magnitude of pesticide-related problems.

Newly identified environmental problems and priorities could have a similar effect on long-term goals. For example, pesticide use is affected by unanticipated outbreaks of pest infestations and/or disease factors, which require EPA to review emergency uses in order to preclude unreasonable risks to the environment. While the Agency can provide incentives for the submission of registration actions such as reduced risk and minor uses, EPA does not control incoming requests for registration actions. As a result, the Agency's projection of regulatory workload is subject to change.

Resource Summary
(Dollars in thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Safe Food	**$113,098.3**	**$109,814.6**	**$119,011.5**	**$9,196.9**
Reduce Risks from Pesticide Residues in Food	$47,447.6	$45,290.4	$43,427.9	($1,862.5)
Eliminate Use on Food of Pesticides Not Meeting Standards	$65,650.7	$64,524.2	$75,583.6	$11,059.4
Total Workyears	781.3	770.1	785.0	14.9

Objective1: Reduce Risks from Pesticide Residues in Food

By 2006, reduce public health risk from pesticide residues in food from pre-Food Quality Protection Act (FQPA) levels (pre-1996).

Resource Summary
(Dollars in Thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Reduce Risks from Pesticide Residues in Food	**$47,447.6**	**$45,290.4**	**$43,427.9**	**($1,862.5)**
Environmental Program & Management	$45,091.3	$42,964.7	$40,504.6	($2,460.1)
Science & Technology	$2,356.3	$2,325.7	$2,923.3	$597.6
Total Workyears	332.6	331.1	339.5	8.4

Key Program
(Dollars in Thousands)

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Endocrine Disruptor Screening Program	$1,860.4	$2,096.3	$2,052.3	($44.0)
Facilities Infrastructure and Operations	$4,725.2	$4,462.6	$4,526.5	$63.9
Homeland Security-Critical Infrastructure Protection	$500.0	$0.0	$0.0	$0.0
Homeland Security-Preparedness, Response and Recovery	$0.0	$0.0	$1,218.3	$1,218.3
Legal Services	$1,019.7	$1,095.3	$1,143.6	$48.3
Management Services and Stewardship	$504.0	$420.6	$450.3	$29.7
Pesticide Registration	$31,832.4	$30,882.2	$25,042.4	($5,839.8)

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Pesticide Reregistration	$6,227.0	$5,673.4	$6,143.8	$470.4
Pesticide Residue Tolerance Reassessments	$813.3	$660.0	$2,806.2	$2,146.2
Planning and Resource Management	$0.0	$0.0	$44.5	$44.5
Safe Pesticide Applications	$25.0	$0.0	$0.0	$0.0

Annual Performance Goals and Measures

Decrease Risk from Agricultural Pesticides

In 2004 Decrease adverse risk from agricultural uses from 1995 levels.

In 2003 Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides that enter the market are safe for humans and the environment, through ensuring that all registration action are timely and comply with standards mandated by law.

In 2002 In FY 2002, EPA continued to register pest control products, including "safer" pesticides, thus ensuring that growers have an adequate number of pest control options available to them.

Performance Measures:	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	
Register safer chemicals and biopesticides	107	118	131	Regist. (Cum)
New Chemicals	60	67	74	Regist. (Cum)
New Uses	2329	2679	3,079	Actions (Cum)
Reduction of detections on a core set of 19 foods eaten by children relative to detection levels for those foods reported in 1994-1996.	Data Not Avail			Reduced Detect.
Percentage of acre-treatments with reduced risk pesticides	7.5%	8.1%	8.5%	Acre-Treatments
Occurrences of residues on a core set of 19 foods eaten by children relative to occurrence levels for those foods reported in 1994-1996.		20	25%	reduc. of occur
Number of new uses for previously registered antimicrobial products			8	new uses

Baseline: The baseline for registration of reduced risk pesticides, new chemicals, and new uses, the baseline is zero in the year 1996 (the year FQPA was enacted). Progress is measured cumulatively since 1996. The baseline for acres-treated is 3.6% of total acreage in 1998, when the reduced-risk pesticide acres-treatments was 30,332,499 and total (all pesticides) was 843,063,644 acre-treatments. Each year's total acre-treatments, reported by USDA's National Agricultural Statistical Survey serve as the basis for computing the percentage of acre-treatments using reduced risk pesticides. Acre-treatments count the total number of pesticide treatments each acre receives each year. The baseline for residues on children's foods is occurrence on 33.5% of composite sample of children's foods in the baseline years 1994-1996. There are currently no products registered for use against other potential bio-agents (non-anthrax).

Baseline: There are currently no products registered for use against other potential bio-agents (non-anthrax).

Verification and Validation of Performance Measures

FY 2004 Performance Measure: Reduction in occurrences of carcinogenic and cholinesterase-inhibiting neurotoxic pesticide residues on a core set of 19 children's foods reported in 1994-1996

Performance Database: United States Department of Agriculture (USDA) Pesticide Data Program (PDP)

Data Source: Data collection is conducted by the states.

Methods, Assumptions and Suitability: The information is collected by the states and includes statistical information on pesticide use, food consumption, and residue detections, which provide the basis for realistic dietary risk assessments and evaluation of pesticide tolerance. Information is coordinated by USDA agencies and cooperating state agencies. Pesticide residue sampling and testing procedures are managed by USDA's Agricultural Marketing Service (AMS). AMS also maintains an automated information system for pesticide residue data and publishes annual summaries of residue detections.

QA/QC Procedures: The core of USDA's PDP's QA/QC program is Standard Operating Procedures (SOPs) based on EPA's Good Laboratory Practices. At each participating laboratory, PDP relies on a quality assurance (QA) unit which operates independently from the rest of the laboratory staff. Final QA procedures are provided by PDP staff responsible for collating and reviewing data for conformance with SOPs. PDP staff also monitors the performance of participating laboratories through proficiency evaluation samples, quality assurance internal reviews, and on site visits.

Data Quality Review: None

Data Limitations: Participation in PDP sites is voluntary. Sampling is limited to 10 states but designed in a manner to represent the food supply nationwide. The number of sampling sites and volume vary by state. Sampling procedures are described at the website, see reference below.

Error Estimate: Uncertainties and other sources of error are minor and not expected to have any significant effect on performance assessment. More information is available on the website.

New/Improved Data or Systems: These are not EPA data; thus improvements are not known in any detail at this time.

References: PDP Annual Reports, http://www.ams.usda.gov/science/pdp/download.htm; http://www.ams.usda.gov/process/; CFR 40 Part 160; http://www.epahome/Standards.html

FY 2004 Performance Measures: Number of registrations of reduced risk pesticides registered (Register safer chemicals and biopesticides).

- **Number of new conventional pesticides registered (New Chemicals).**
- **Number of conventional new uses registered (New Uses).**

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the program divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and record keeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers) update the status of the submissions and studies as they are received and as work is completed by the reviewers. The status indicates whether the application is ready for review, the application is in the process of review, or the review has been completed.

Methods, Assumptions and Suitability:
The measures are program outputs. When finalized they represent the program's statutory requirements to ensure: 1) that pesticides entering the marketplace are safe for human health and the environment and 2) when used in accordance with the packaging label present a reasonable certainty of no harm. While program outputs are not the best measures of risk reduction, they do provide a means for reducing risk in that the program's safety review prevents dangerous pesticides from entering the marketplace.

QA/QC Procedures: A reduced risk pesticide must meet the criteria set forth in Pesticide Registration Notice 97-3, September 4, 1997. Reduced risk pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced risk). All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review.

Data Quality Review: These are program outputs. EPA staff and management review the program outputs in accordance with established policy for the registration of reduced-risk pesticides as set forth in Pesticide Regulation Notice 97-3, September 4, 1997.

Data Limitations: None. All required data must be submitted for the risk assessments before the pesticide, including a reduced risk pesticide, is registered. If data are not submitted, the pesticide is not registered. As stated above, a reduced risk pesticide must meet the criteria set forth in PRN 97-3 and all registrations must meet FQPA safety requirements. If a pesticide does not meet these criteria, it is not registered. If an application for a reduced risk pesticide does not meet the reduced risk criteria, it is reviewed as a conventional active ingredient.

Error Estimate: N/A

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003, after which the system will be reevaluated to ensure that it is meeting program needs.

References: FIFRA Sec 3(c)(5); FFDCA Sec 408(a)(2); EPA Pesticide Registration Notice 97-3, September 4, 1997

FY 2004 Performance Measure: Percentage of acre treatments with reduced risk pesticides.

Performance Database: Two non-EPA databases are used for this measure. One is the Doane Marketing Research data, the other is the United States Department of Agriculture's (USDA) National Agricultural Statistical Survey (NASS) database.

Data Source: Doane Marketing Research (a private sector research database) and USDA surveys (e.g., NASS data).

Methods, Assumptions and Suitability: A reduced-risk pesticide must meet the criteria set forth in Pesticide Registration Notice 97-3, September 4, 1997. Reduced-risk pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water, or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced-risk).

EPA's statistical and economics staff review data from Doane and NASS. Information is also compared to prior years for variations and trends as well as to determine the reasons for the variability.

QA/QC Procedures: All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review. Doane data and USDA's NASS data are subject to extensive QA/QC procedures, documented at their websites. Additionally, Doane and NASS information are compared as a cross-reference.

Data Quality Review: Doane data and USDA's NASS data are subject to extensive internal quality review, documented at their websites. EPA's statistical and economics staff review data from Doane and NASS. Information is also compared to prior years for variations and trends as well as to determine the reasons for the variability.

Data Limitations: Doane data are proprietary; thus in order to release any detailed information, the Agency must obtain approval. The NASS data include only major crops for annual surveys. Other crops are surveyed biennially. Additionally, all states are not included, although those that are a representative sample of the nation.

New/Improved Data or Systems: These are not EPA databases; thus improvements are not known in any detail at this time.

Error Estimate: Error estimates differ according to the data/database and year of sampling. Doane sampling plans and QA/QC procedures are available to the public at their website. More specific information about the data is proprietary and a subscription fee is required. Data are weighted and multiple regression procedure is used to adjust for known disproportionalities and ensure consistency with USDA and state acreage estimates. NASS data reliability and sampling/estimating techniques also are discussed at their website.

References: OPP Website; OPP Annual Report; Annual Performance Plan and Annual Performance Report, http://www.ams.usda.gov/science/pdp/download.htm; Doane Marketing Research, Inc.: http://www.doanemr.com; http://www.usda.gov/nass/pubs and http://www.usda.nass/nass/nassinfo; FFDCA Sec 408(a)(2); EPA Pesticide Registration Notice 97-3, September 4, 1997.

Statutory Authorities

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Objective 2: Eliminate Use on Food of Pesticides Not Meeting Standards

By 2008, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be eliminated.

Resource Summary
(Dollars in Thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Eliminate Use on Food of Pesticides Not Meeting Standards	**$65,650.7**	**$64,524.2**	**$75,583.6**	**$11,059.4**
Environmental Program & Management	$53,660.0	$52,478.3	$62,288.6	$9,810.3
Science & Technology	$11,990.7	$12,045.9	$13,295.0	$1,249.1
Total Workyears	448.7	439.0	445.5	6.5

Key Program
(Dollars in Thousands)

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Endocrine Disruptor Screening Program	$3,388.7	$3,264.1	$3,275.1	$11.0
Facilities Infrastructure and Operations	$4,575.2	$5,154.0	$6,311.8	$1,157.8
Homeland Security-Critical Infrastructure Protection	$500.0	$0.0	$0.0	$0.0
Homeland Security-Preparedness, Response and Recovery	$14.0	$0.0	$0.0	$0.0
Legal Services	$433.5	$465.5	$486.0	$20.5
Management Services and Stewardship	$931.5	$854.6	$904.6	$50.0

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Pesticide Reregistration	$27,170.8	$38,592.4	$41,207.7	$2,615.3
Pesticide Residue Tolerance Reassessments	$13,858.5	$4,607.9	$10,004.3	$5,396.4
Planning and Resource Management	$0.0	$0.0	$46.0	$46.0
Research to Support FQPA	$11,377.4	$10,821.3	$12,041.9	$1,220.6
Science Coordination and Policy	$315.1	$764.4	$1,306.2	$541.8

Annual Performance Goals and Measures

Reassess Pesticide Tolerances

In 2004 Ensure that through on-going data reviews, pesticide active ingredients and the products that contain them are reviewed to assure adequate protection for human health and the environment, taking into consideration exposure scenarios such as subsistence lifestyles of Native Americans.

In 2003 Assure that pesticides active ingredients registered prior to 1984 and the products that contain them are reviewed to assure adequate protection for human health & the environment. Also consider the unique exposure scenarios such as subsistence lifestyles of Native Americans in regulatory decisions.

In 2002 Reregistration efforts delayed to focus on reviewing and testing pesticides against anthrax.

Performance Measures:	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	
Tolerance Reassessment	66.9	68%	78%	Tolerances(Cum)
Reregistration Eligibility Decisions (REDs)	72.7%	76%	81.7%	Decisions (Cum)
Product Reregistration	307	400	750	Actions
Tolerance reassessments for top 20 foods eaten by children	65.6	75%	83%	Tolerances(Cum)
Number of inert ingredients tolerances reassessed			100	tolerances

Baseline: The baseline value for tolerance reassessments is the 9,721 tolerances that must be reassessed using FQPA health and safety standards. In FY2004, EPA plans to reassess 1,050 additional tolerances. The baseline for REDS is the 612 REDs that must be completed. In FY2004, EPA plans to complete 35 REDs. The baseline for product reregistration is under development. The baseline for inert tolerances is 870 that must be reassessed. The baseline for the top 20 foods eaten by children is 893 tolerances that must be reassessed.

Verification and Validation of Performance Measures

FY 2004 Performance Measures:

- **Number of Tolerance Reassessments issued.**
- **Number of Reregistration Eligibility Decisions (REDs) issued.**
- **Number of Product Reregistration decisions issued.**

- **Tolerance Reassessments for top 20 foods eaten by children**

- **Number of inert ingredients tolerances reassessed.**

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the program divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and record keeping.

Data Source: Office of Pesticide Programs' reviewers. Methods, Assumptions and Suitability: The measures are program outputs which represent the program's statutory requirements to ensure that pesticides entering the marketplace are safe for human health and the environment and when used in accordance with the packaging label present a reasonable certainty of no harm. While program outputs are not the best measures of risk reduction, they do provide a means for reducing risk in that the program's safety review prevents dangerous pesticides from entering the marketplace.

QA/QC Procedures: All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review.

Data Quality Review: Management reviews the program counts and signs off on the decision document, which is then forwarded to the Office Director.

Data Limitations: None known.

Error Estimate: N/A. There are no errors associated with count data.

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various Pesticides program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003, after which the system will be reevaluated to ensure that it is meeting program needs.

References: Office of Pesticide Programs (OPP) Website; OPP Annual Report; Annual Performance Plan and Annual Performance Report

Research

The research program of the National Institute of Environmental Health and Safety (NIEHS) is closely allied with that of EPA's in studying the impact of environmental contaminants on public health. Under their extramural programs, EPA and NIEHS jointly sponsor Centers for Children's Environmental Health and Disease Prevention Research. The centers conduct research to improve detection, treatment, and prevention of environmentally related diseases in children.

The National Institute for Child Health and Human Development (NICHD) supports research on the reproductive, neurobiological, developmental, and behavioral processes that determine and maintain the health of children and adults. The NICHD program includes research on the effects of exposure to environmental agents on human development. NICHD, EPA, CDC, and other Federal agencies are designing the National Children's Study, a large longitudinal epidemiology study of children's exposure to environmental agents. EPA and NICHD jointly sponsor research on genetic susceptibility and variability of human malformations. EPA's efforts in this area focus on identifying environmental agents that cause birth defects and other developmental disorders, the molecular mechanisms of birth defects, and how to use mechanistic and other data in the risk assessment process.

The National Cancer Institute's (NCI) Agricultural Health Study (AHS) is a large epidemiology study of cancer in farm workers and their families. EPA is participating in the AHS through an exposure study of a subgroup of participants. CDC's National Center for Health Statistics (NCHS) is conducting the fourth National Health and Nutrition Examination Survey (NHANES IV), a national survey of health and nutrition. The NHANES surveys have about 30,000 respondents and include sufficient numbers of children in selected age ranges and other potentially sensitive subgroups to allow statistical inferences about their health, nutrition, and food intake, and the concentrations of some environmental contaminants in their blood and

urine. EPA is collaborating with NCHS to collect information on children's exposure to pesticides and other environmental contaminants. NHANES has been conducted since 1971.

Statutory Authorities:

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Toxic Substances Control Act (TSCA)